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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/663,265		MATHIOWITZ ET AL.	
	Examiner		Art Unit	
	Maria Leavitt		1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Status of claims. The specification has been amended; claims 3-15 have been amended and claim 18 has been cancelled by amendment dated February 17, 2006.

Response to arguments

3. Withdrawn rejections in response to Applicant arguments or amendments

In response to Applicant's amendment of the word "system " by the word "composition" in claims 3-14, the examiner has considered the argument persuasive.

In response to Applicant's amendment of the word "naked DNA " by the word "gene" in claims 3, 8, 9, 10, 11, 14, and 15, the examiner has considered the argument persuasive.

In response to Applicant's amendment of the phrase "consisting of stents, coating, slabs, and films " by the phrase "in the form of a stents, coating, slabs, gels and films" in claim 3, the Examiner has considered the argument persuasive.

Rejections under 35 U.S.C. 102

Rejections under 102 over U.S. Patent No. 5,639,473 to Grinstaff et al., or U.S. Patent No. 5,763,416 to Bonadio et al., have been withdrawn in view of the attached Declaration under 37 C.F. R. 1.131.

Rejections under 102 over Tice and al., has been withdraw as the Examiner has considered Applicants arguments persuasive.

Rejections under 35 U.S.C. 103

Rejections under 103 over US. Patnet No 5,770,580 to Ledley in combination with Grinstaff et al., or Bonadio and al., has been withdrawn as the Examiner has considered Applicants arguments persuasive.

4. Remaining rejections in response to Applicant arguments or amendments

35 U.S.C. 112, first paragraph, written

Claim 17 remains rejected udder 35 U.S.C. 112, first paragraph.

In response to applicant's assertion (Remarks, p. 4) that Claim 17 recites the limitation, " the polymeric matrix is formed after implantation into the mammalian subject" which finds not writing support from the as-filed application, the comment is not found persuasive.

As indicated in the previous Office action, the closest reference as to the way of polymerizing the monomers and DNA into a polymer after implantation, is be UV light in vivo without damaging the DNA in the subject. Applicant states that the system referred to on page 13, line 18, is a diacrylated-poly(lactide-co-glycolide)-PEG polymer that is FDA approved. It is not clear how the expected lack of DNA damage in a polymer crosslinked by UV light without containing DNA, can be extrapolated to an *in vivo* system wherein the polymer comprises DNA and UV light to form the polymer should be applied after implantation. Further, the Declaration under 37 C. F. R. 1.131 supports the formation of a polymer precipitate with DNA which is implanted as DNA/PLA pellets in the left and right legs of the incised rat muscles. Hence the

Declaration does not address the formation of the polymeric matrix after implantation into the mammalian subject and therefore, it is not commensurate in scope with the invention of claim 17. Thus, it appears that there are not *in vivo* working examples present in the as-filed application that provides factual evidence drawn to polymerization of a matrix after implantation from experiments conducted by applicants. Hence, rejection of claim 17 is maintained.

Rejection, Obviousness Type Double Patenting-No secondary Reference(s)

Claims 3-17 remain rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 and 2 of U. S. Patent No. 6,620,617, filing date March 23, 2001; over claims 1-8 of U. S. Patent No. 6,475,779, filing date Oct. 15, 1998 and over claims 1-14 of U. S. Patent No. 6,262,034, filing date Nov. 25, 1997.

In response to applicant's arguments that double patenting reflection seems to be base on the premise that the claims in U. S. Patent No. 6,620,617, U. S. Patent No. 6,475,779 and U. S. Patent No. 6,262,034, are all related to polymeric microspheres containing DNA and that such microspheres make obvious polymeric slabs, films, coatings, gels or stents, the comment is not found persuasive.

The Examiners notes that the use of slabs, films, coatings, gels or stents is an obvious alternate embodiment of the invention because it is disclosed in the specification on pp. 5, lines 20-21 and p. 13, lines 13-16. Thus no secondary reference is necessary to make obvious the alternate embodiment as disclosed in the file-application.

Thus, Claims 3-17 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U. S. Patent No. 6,620,617,

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filing date March 23, 2001; over claims 1-8 of U. S. Patent No. 6,475,779, filing date Oct. 15, 1998 and over claims 1-14 of U. S. Patent No. 6,262,034, filing date Nov. 25, 1997, for the reasons of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 112- First paragraph- New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3 recites the limitation "loaded into the polymeric matrix at a concentration between about 0.01 and 90% and is". The specification discloses on p. 22, lines 9-19, that 100 ul of either circular or linear DNA (between 1 and 2 mg/ml diluted 1:5 in buffer) was introduced into the aliquots containing the mixtures of 1 g PLA and 2 g PLA that has been dissolved in 10 ml of methylene chloride and 5 drops of Span 85. No other teachings are anticipated about the encapsulation of linear and supercoiled DNA in a PLA blend. Thus is not clear that the Applicant was in possession of a genus of undefined polymeric matrix at a concentration between about 0.01 and 90% at the time of filing.

Claim 3 will remain rejected until Applicant cancels all new matter.

Claim Rejections - 35 USC § 102e

The following is a quotation of the appropriated paragraphs of 35 U.S.C. 102 that forms the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraph (1), (2) and (4) of section 371© of this title before the invention thereof by the applicant for patent.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-7, 9-13 and 15-17 are rejected under 35 U.S.C. 102(e) as being unpatentable over Ledley et al., (US Patent No. 5,770,580, filing date May 30, 1995).

Claim 3 of the instant application is interpreted as a composition for gene delivery, the composition comprising a polymeric matrix and a DNA dispersed within the polymeric matrix. The dispersed amount of DNA when given the broadest possible interpretation is interpreted as an amount of DNA coding a protein that is effectively expressed as to have a therapeutic effect. Ledley et al., teach a method for gene delivery (e.g., release) and transient gene expression

comprising the steps of administering formulated DNA expression vectors to cells associated with fluid spaces *in vivo* under conditions in which cells associated with the fluid space incorporate the formulated DNA expression vector (abstract, and claim 1). Ledley et al., disclose that the method has been able to achieve significant levels of expression by directly injecting formulated DNA vectors into cells associated with fluid spaces (e.g., joints, thyroid, ear and eye) and express recombinant genes at levels comparable to levels seen in muscle (column 6, lines 13-16). Ledley et al., further teach that the method allows use of genes as medicines that can be administered intermittently in response to acute disease or over the long term to establish steady state levels of a therapeutic gene product, and thus, genes can be used in clinical practice (column 6, lines 35-41). Ledley et al., disclose *in vivo* cells and tissues affected by the gene transfer method, e.g., synovial cells, chondrocytes, extracellular matrix or cartilage, bone, periosteum of bone, inflammatory cells resulting from inflammatory processes, lymphocytes, mast cells, monocytes, eosinophils, fibroblasts (column 7, lines 40-55), and cells associated with enhancement of repair, regeneration, and recovery of essential structures of the joint (column 16, last paragraph). More specifically, Ledley teaches that the formulated DNA expression vectors with formulated elements include gels, slow release matrices soluble or insoluble particles, as well as other formulation elements not listed (col. 8, lines 42-47; col. 14, lines 10-15; col. 35, lines 15-21, which enhance the delivery, uptake, stability, and expression of genetic material into cells. Genes employed in the method of Ledley include genes encoding collagens, extracellular matrix proteins, IL-1, IL-4, growth factors, enzymes for synthesis and secretion of synovial fluid, hormones, receptors and cytokines (paragraph bridging column 9 and 10).

Thus, Ledley teaches all the claimed limitations and Anticipates Applicant's claimed invention.

Claim Objections

Claim 15 is objected to as being dependent upon claim 4 and reciting the term "system" which is not found in claim 4.

Information Disclosure Statement. No copy of References.

The information disclosure statement filed 02-02-2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Only legible copies of non-patent literature provided in the instant application or parent U.S. patent No. 6,620,617 and parent U.S. patent No. 6,262,034 are considered. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Those citations not considered by the examiner will have a line drawn through the citation and citations considered will have the examiner's initial adjacent thereto. A submission of a legible copy of each cited non-patent literature publication or that portion which caused it to be listed is required for examination.

Conclusion

Applicant response file on February 17, 2006 has been considered by the Examiner but is moot in view of the new grounds of the rejection, which is necessitated by the claims amendment.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nguyen Dave can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Epps-Ford
Primary Examiner
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